

JUL 12 2000

K801421

510(k) Summary

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Jennifer Tribbett

Date Prepared: May 31, 2000

2) Device Name Proprietary Name: OnTrak TesTcup 5₀₁

Classification Name	Code	CFR	Predicate Device Name	Predicate 510(k) Number
Amphetamines Test System	91DKZ	862.3100	OnTrak TesTcup	K962411
Cocaine Test System	91DIO	862.3250	OnTrak TesTcup	K962411
Cannabinoids Test System	91LDJ	862.3870	OnTrak TesTcup	K962411
Morphine Test System	91DJJ	862.3640	OnTrak TesTcup	K962411
Methamphetamine Test System	91LAF	862.3610	OnTrak TesTstik Methamphetamine	K000096

3) Predicate device We claim substantial equivalence to the currently marketed devices indicated above.

Continued on next page

4) Device Description

The OnTrak TesTcup 5₀₁ assay contained in this submission is an *in vitro* diagnostic test intended for professional use in the qualitative detection of amphetamines (1000 ng/ml), cocaine (300 ng/ml), morphine (300 ng/ml), THC (50 ng/ml) and methamphetamine (500 ng/ml) in urine.

The TesTcup assays are based on the principle of microparticle capture inhibition. The test relies on the competition between drug, which may be present in the urine being tested, and drug conjugate immobilized on a membrane in the test chamber.

Urine is collected directly in the OnTrak TesTcup 5₀₁. After closing the cap and moving it to the "TEST" position, the sample reservoir is filled by tilting the cap. Urine then flows through a membrane by capillary action and reacts with antibody-coated microparticles and drug conjugate present on the membrane. In the absence of drug, the antibody is free to interact with the drug conjugate, causing the formation of a blue band ("negative" sign).

When drug is present in the specimen, it binds to the antibody-coated microparticles. If sufficient drug is present, the micro-particles are inhibited from binding the drug conjugate and no blue band is formed at the result window. A positive sample caused the membrane to remain white ("positive" sign).

An additional antibody/antigen reaction occurs at the "TEST VALID" area. The "TEST VALID" blue band forms when antibodies, which are imbedded in the reagent membrane, bind to the antigen on the blue microparticles. The presence of the "TEST VALID" band indicates that the test has completed, the reagents in the "TEST VALID" area are valid, and the results are ready to interpret.

5) Technology Characteristics

TesTcup 5₀₁ contains five individual, independent test chambers where the membranes, immobilized with the drug conjugates, are inserted. Each individual membrane contained in the TesTcup 5₀₁ device has been previously reviewed by FDA under the 510(k) numbers indicated in section 2 of this 510(k) summary.

In other words, the same functional membranes (strips) for Amphetamines, Cocaine, THC, Morphine and Methamphetamine contained in the predicate devices have now been inserted into the TesTcup 5₀₁ chambers.

Continued on next page

**6) Substantial
Equivalence**

The TesTcup 5₀₁ device has the **same intended use** and incorporates the **same fundamental scientific technology** as the predicate devices.

Topic	OnTrak TesTcup 5 ₀₁	Predicates: OnTrak TesTcup and TesTstik Methamphetamine
Intended Use	Qualitative detection of amphetamines, cocaine metabolites, cannabinoids, morphine and methamphetamine in urine.	Same
Scientific Technology	Microparticle capture inhibition	Same
Sample Matrix	Urine	Same



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 12 2000

Ms. Jennifer Tribbett
Regulatory Affairs Specialist
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana

Re: K001421
Trade Name: OnTrak TesTcup 5₀₁
Regulatory Class: II
Product Code: DKZ, DIO, LDJ, DJJ, LAF
Dated: May 31, 2000
Received: June 7, 2000

Dear Ms. Tribbett:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

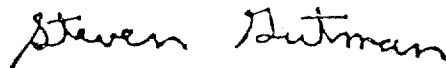
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K001421

510(k) Number (if known):

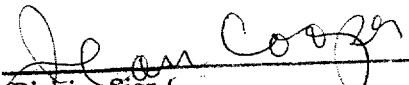
Device Name: OnTrak TesTcup 5₀₁

Indications for Use:

OnTrak TesTcup 5₀₁ is an in-vitro diagnostic test intended for professional use for the qualitative detection of amphetamine (1000 ng/ml), cocaine (300 ng/ml), morphine (300 ng/ml), THC (50 ng/ml) and methamphetamine (500 ng/ml) in urine.

OnTrak TesTcup 5₀₁ provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmation method.

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001421

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)